PTO/SB/08A (08-03)

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 6

Complete If Known	
Application Number	10/823,932
Filing Date	April 13, 2004
First Named Inventor	Nielsen et al.
Art Unit	~~Unassigned~~ 1633
Examiner Name	~~Unassigned~~ Priebe, S.
Attorney Docket Number	016930-003713US

U.S. PATENT DOCUMENTS+

Examiner Initials*	Cite No.[1]	Document Number Number Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
SP	AA	5,498,731	5/5/1996	Xu, et al.	
	AB	5,747,469	5/5/1998	Roth, et al.	
	AC	6,054,487	04/25/2000	Gjerset	
	AD	6,262,032	07-17-2001	Tocque	
	AE	6,316,462 B1	11/13/2001	Bishop, et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]	Number[4]	Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
SP	AF	WO	94/06910		03/31/1994			☐
	AG	WO	95/05738		03/05/1995			☐
	AH	WO	95/11984		05/1995			☐
	AI	WO	98/21456		07/1998			
	AJ	WO	97/23478		07/1997			
	AK	EP	0685493		12/06/1995			
	AL	EP	0727486		08/21/1995			☐

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] Kind Codes of U.S. Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449B/PTO	Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application Number	10/823,932
	Filing Date	April 13, 2004
	First Named Inventor	Nielsen et al.
	Art Unit	Unassigned
(use as many sheets as necessary)	Examiner Name	Unassigned
Sheet 2 of 7	Attorney Docket Number	016930-003713US

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials *		Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
SP		AM	Alberts, et al., (1997) "Safety aspects of Pegylated liposomal Doxyrubicin in Patients with Cancer," Drugs 54 Suppl. 4 30-35.	
		AN	Allan, *et al., Scanning Microsc.* 2:503 (1988)	
		AO	Allen, T. M., (1997) "Liposomes," Drugs 54 Suppl. 4 8-14.	
		AP	Anderson, W.F., "Human gene therapy," *Nature* 392(6679 Suppl):25-30 (1998)	
		AQ	Baxter, et al., "Cell death by apoptosis in acute leukaemia." J Pathol. 1989 Jun;158(2):123-9.	
		AR	Blagosklonny, *et al.*, "In Vitro Evaluation of A *p53*-Expressing Adenovirus As An Anti-Cancer Drug," *Int. J. Cancer* 67:386-392 (1996)	
		AS	Brinckerhoff, et al., Regulatory Issues: Dept. of Health and Human Services NIH Recombinant DNA Advisory Committee Minutes of Meeting. *Human Gene Therapy* 6(8): 1065-1124 (1995)	
		AT	Bulinski J, et al. "Overexpression of MAP4 inhibits organelle motility and trafficking in vivo." J Cell Sci. 1997 Dec; 110(Pt 24): 3055-3064.	
		AU	Chang, *et al.*, "Restoration of the G_1 Checkpoint and the Apoptotic Pathway Mediated by Wild-type *p53* Sensitizes Squamous Cell Carcinoma of the Head and Neck to Radiotherapy," *Arch Otolaryngol Head Neck Surg.*, 123:507-512 (1997)	
		AV	Chen, et al., , "Genetic mechanisms of tumor suppression by the human p53 gene." Science. 1990 Dec 14;250(4987):1576-80.	
		AW	Clarke, et al, "Thymocyte apoptosis induced by p53-dependent and independent pathways." Nature. 1993 Apr 29;362(6423):849-52.	
		AX	Clayman *et al.*, "Adenovirus-mediated p53 gene transfer in patients with advanced recurrent head and neck squamous cell carcinoma," *Journal of Clinical Oncology* 16(6):2221-2232 (1998)	
		AY	Columbano, et al., "Occurrence of cell death (apoptosis) in preneoplastic and neoplastic liver cells. A sequential study." Am J Pathol. 1984 Sep;116(3):441-6.	
		AZ	Dass CR, et al. "Enhanced anticancer therapy mediated by specialized liposomes." J Pharm Pharmacol. 1997 Oct; 49(10): 972-975.	
		BA	Delia, et al., "p53 Activity and Chemotherapy." *Nature Medicine* 2(7):724-725 (1996)	
		BB	Denning C, et al. "Bystander effects of different enzyme-prodrug systems for cancer gene therapy depend on different pathways for intercellular trans fer of toxic metabolites, a factor that will govern clinical choice of appropriate regimes. Hum Gene Ther. 1997 Oct 10; 8(15): 1825-1835.	

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Substitute for form 1449B/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 3 of 6

Complete if Known	
Application Number	10/823,932
Filing Date	April 13, 2004
First Named Inventor	Nielsen et al.
Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	016930-003713US

NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
SP	BC	Donehower, et al., *The Cancer Bulletin* 46:161 (1994), p. 165.	
	BD	Drazan, *et al., Surgery* 116:197 (1994)	
	BE	Frank, *et al.*, "Combination *E2F-1* and *p53* Gene Transfer Does Not Enhance Growth Inhibition in Human Squamous Cell Carcinoma of the Head and Neck," *Clin. Cancer Research* 4:2265-2272 (1998)	
	BF	Fujiwara, et al., (1994) Curr. Opin. Oncol. 6:96	
	BG	Fujiwara, *et al.*, "Induction of chemosensitivity in human lung cancer cells *in Vivo* by adenovirus-mediated transfer of the wild-type p53 gene," *Cancer Research* 54:2287-2291 (1994)	
	BH	Gallardo, *et al.*, "Adenovirus-based Transfer of Wild-Type *p53* Gene Increases Ovarian Tumor Radiosensitivity," *Cancer Research* 56:4891-4893 (1996)	
	BI	Gjerset, *et al.*, "Use of Wild-Type *p53* to Achieve Complete Treatment Sensitization of Tumor Cells Expressing Endogenous Mutant p53," *Molecular Carcinogenesis* 14:275-285 (1995)	
	BJ	Gobe, et al., "Cell death by apoptosis following X-irradiation of the foetal and neonatal rat kidney." Int J Radiat Biol. 1988 Oct;54(4):567-76.	
	BK	Gumani, *et al.*, "Adenovirus-mediated p53 gene therapy has greater efficacy when combined with chemotherapy against human head and neck, ovarian, prostate, and breast cancer," *Cancer Chemother Pharmacol.* 44:143-151 (1999)	
	BL	Harris, Curtis C. *et al.*, "Structure and function of the p53 tumor suppressor gene: clues for rational cancer therapeutic strategies," *Journal of the National Cancer Institute* 88(20):1442-1455 (1996)	
	BM	Hehir *et al.*, "Molecular characterization of replication-competent variants of adenovirus vectors and genome modifications to prevent their occurrence." *J Virol.* 70(12):8459-8467 (1996)	
	BN	Ijiri, et al., "Apoptosis (cell death) induced in mouse bowel by 1,2-dimethylhydrazine, methylazoxymethanol acetate, and gamma-rays." Cancer Res. 1989 Nov 15;49(22):6342-6.	
	BO	Ijiri, et al., "Cell death (apoptosis) in mouse intestine after continuous irradiation with gamma rays and with beta rays from tritiated water." Radiat Res. 1989 Apr;118(1):180-91.	
	BP	Kalechman, et al., "The antitumoral effect of the immunomodulator AS101 and paclitaxel (Taxol) in a murine model of lung adenocarcinoma." *J Immunol.* 156(3):1101-1109 (1996	
	BQ	Kianmanesh AR, et al. "A "distant" bystander effect of suicide gene therapy: regression of nontransduced tumors together with a distant transduced tumor." Hum Gene Ther. 1997 Oct 10; 8(15): 1807-1814.	
	BR	Lanni, et al., "p53-independent apoptosis induced by paclitaxel through an indirect mechanism. Proc Natl Acad Sci U S A. 1997 Sep 2;94(18):9679-83.	
↓	BS	Lechanteur C, et al. "HSV-1 thymidine kinase gene therapy for colorectal adenocarcinoma-derived peritoneal carcinomatosis." Gene Ther. 1997 Nov; 4(11): 1189-1194.	

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				First Named Inventor	Nielsen et al.
				Art Unit	Unassigned
(use as many sheets as necessary)				Examiner Name	Unassigned
Sheet	4	of	6	Attorney Docket Number	016930-003713US

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SP		BT	Liu, et al., "Growth suppression of human head and neck cancer cells by the introduction of a wild-type p53 gene via a recombinant adenovirus." Cancer Res. 1994 Jul 15;54(14):3662-7.	
		BU	Lopes NM, et al. "Assessment of microtubule stabilizers by semiautomated in vitro microtubule protein polymerization and mitotic block assays. " Cancer Chemother Pharmacol. 1997; 41(1): 37-47.	
		BV	Lowe, et al., "p53-dependent apoptosis modulates the cytotoxicity of anticancer agents." Cell. 1993 Sep 24;74(6):957-67.	
		BW	Mallams AK, et al. "Antitumor 8-chlorobenzocycloheptapyridines: a new class of selective, nonpeptidic, nonsulfhydryl inhibitors of ras farnesylation. " Bioorg Med Chem. 1997 Jan; 5(1): 93-99.	
		BX	Muhlradt PF, et al. "Epothilone B stabilizes microtubuli of macrophages like taxol without showing taxol-like endotoxin activity." Cancer Res. 1997 Aug 15; 57(16): 3344-3346.	
		BY	Nguyen, *et al.*, "Gene therapy for lung cancer: enhancement of tumor suppression by a combination of sequential systemic cisplatin and adenovirus-mediated p53 gene transfer," *J. Thorac. Cardiavasc. Surg.* 112:1372-1377 (1996)	
		BZ	Nielsen and Maneval, "p53 tumor suppressor gene therapy for cancer," *Cancer Gene Therapy* 5(1):52-63 (1998)	
		CA	Nielsen, *et al.* "Adenovirus-mediated *p53* Gene Therapy and Paclitaxel Have Synergistic Efficacy in Models of Human Head and Neck, Ovarian, Prostate, and Breast Cancer," *Clin. Cancer Research* 4:835-846 (1998)	
		CB	Nielsen *et al.*, "Combination therapy with the farnesyl protein transferase inhibitor SCH66336 and SCH58500 (p53 adenovirus) in preclinical cancer models," *Cancer Research* 59:5898-5901 (1999)	
		CC	Nikiforov MA, et al. "Suppression of apoptosis by bcl-2 does not prevent p53-mediated control of experimental metastasis and anchorage dependence." Oncogene. 1997 Dec 18; 15(25): 3007-3012.	
		CD	Njoroge FG, et al. "Structure-activity relationship of 3-substituted N-(pyridinylacetyl)-4- (8-chloro -5,6-dihydro -11H-benzo[5,6]cyclohepta[1,2-b]pyridin-11-ylidene)- piperidine inhibitors of farnesyl-protein transferase: design and synthesis of in vivo active antitumor compounds." J Med Chem. 1997 Dec 19; 40(26): 4290-4301.	
		CE	Ogawa, *et al.*, "Novel combination therapy for human colon cancer with adenovirus-mediated wild-type p53 gene transfer and DNA-damaging chemotherapeutic agent," *Int. J. Cancer* 73:367-370 (1997)	
		CF	Ono Y, et al. "Regression of experimental brain tumors with 6-thioxanthine and Escherichia coli gpt gene therapy" Hum Gene Ther. 1997 Nov 20; 8(17): 2043-2055.	
		CG	Orkin and Motulsky, "Report and recommendations of the panel to assess the NIH investment in research on gene therapy" [online], December 7, 1995 ~~http://www.nih.gov/news/panelrep.html~~	
		CH	Panda D, et al. "Stabilization of microtubule dynamics by estramustine by binding to a novel site in tubulin: a possible mechanistic basis for its antitumor action." Proc Natl Acad Sci U S A. 1997 Sep 30; 94(20): 10560-10564.	
✓		CI	Panda D, et al. "Differential effects of vinblastine on polymerization and dynamics at opposite microtubule ends." J Biol Chem. 1996 Nov 22; 271(47): 29807-29812.	

Examiner Signature		Date Considered	

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(use as many sheets as necessary)

Sheet 5 of 6

Complete If Known	
Application Number	10/823,932
Filing Date	April 13, 2004
First Named Inventor	Nielsen et al.
Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	016930-003713US

NON PATENT LITERATURE DOCUMENTS

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SP	CJ	Parsels, *et al.*, "Prevention of Fluorodeoxyuridine-Induced Cytotoxicity and DNA Damage in HT29 Colon Carcinoma Cells by Conditional Expression of Wild-Type p53 Phenotype," *Molecular Pharmacology* 52:600-605 (1997)	
	CK	Pirollo, *et al.*, "p53 mediated sensitization of squamous cell carcinoma of the head and neck to radiotherapy," *Oncogene*, 14:1735-1746 (1997)	
	CL	Qazilbash MH, et al. "Cancer gene therapy using a novel adeno-associated virus vector expressing human wild-type p53." Gene Ther. 1997 Jul; 4(7): 675-682.	
	CM	Rabinovitch A, et al. "Combination therapy with cyclosporine and interleukin-4 or interleukin-10 prolongs survival of synergeneic pancreatic islet grafts in nonobese diabetic mice." Transplantation. 1997 Dec 15; 64(11): 1525-1531.	
	CN	Reid *et al.*, "Intravascular adenoviral agents in cancer patients: Lessons from clinical trials," *Cancer Gene Therapy* 9:979-986 (2002)	
	CO	Roth et al., (1996) Modification of tumor suppressor gene expression and induction of apoptosis in non-small cell lung cancer (NSCLC) with an adenovirus vector expressing wildtype p53 and cisplatin. Hum Gene Ther. 1996 May 20;7(8):1013-30	
	CP	Roth, *Proc. Am. Ass'n Cancer Res.* 35:692 (1994).	
	CQ	Sarraf, et al., "Kinetic studies on a murine sarcoma and an analysis of apoptosis." Br J Cancer. 1986 Dec;54(6):989-98.	
	CR	Sandig, *et al.*, "Adenovirally transferred *p16*$^{INK4/CDKN2}$ and *p53* genes cooperate to induce apoptotic tumor cell death," *Nature Med.*, 3:313-319 (1997)	
	CS	Schuler *et al.*, "A phase I study of adenovirus-mediated wild-type *p53* gene transfer in patients with advanced non-small cell lung cancer," *Human Gene Therapy* 9:2075-2082 (1998)	
	CT	Seth, et al., "A recombinant adenovirus expressing wild type p53 induces apoptosis in drug-resistant human breast cancer cells: A gene therapy approach for drug-resistant cancers." Cancer Gene Ther. 1997 Nov-Dec;4(6):383-90.	
	CU	Shaw, et al., ."Induction of apoptosis by wild-type p53 in a human colon tumor-derived cell line." Proc Natl Acad Sci U S A. 1992 May 15;89(10):4495-9.	
	CV	Son, *et al.* "Exposure of human ovarian carcinoma to cisplatin transiently sensitizes the tumor cells for liposome-mediated gene transfer," *Proc. Natl. Acad. Sci. USA*, 91:12669-12672 (1994)	
	CW	Spitz, *et al.*, "Adenoviral-mediated Wild-Type *p53* Gene Expression Sensitizes Colorectal Cancer Cells to Ionizing Radiation," *Clin. Cancer Research* 2:1665-1671 (1996)	
	CX	Spitz, *et al.*, "*In Vivo* Adenovirus-Mediated p53 Tumor Suppressor Gene Therapy for Colorectal Cancer," *Anticancer Research*, 18:3415-3422 (1998)	
↓	CY	Su H, et al. "Tissue-specific expression of herpes simplex virus thymidine kinase gene delivered by adeno-associated virus inhibits the growth of human hepatocellular carcinoma in athymic mice. Proc Natl Acad Sci U S A. 1997 Dec 9; 94(25): 13891-13896.	

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				Filing Date	April 13, 2004
				First Named Inventor	Nielsen et al.
				Art Unit	Unassigned
(use as many sheets as necessary)				*Examiner Name*	Unassigned
Sheet	6	of	6	*Attorney Docket Number*	016930-003713US

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials *		Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
SP		CZ	Tishler and Lamppu, "The interaction of taxol and vinblastine with radiation induction of p53 and $p21^{WAF1/CIP1}$," *Br J Cancer* 74(Suppl XXVII):S82-S85 (1996).	
		DA	Vasquez RJ, et al. "Nanomolar concentrations of nocodazole alter microtubule dynamic instability in vivo and in vitro." Mol Biol Cell. 1997 Jun; 8(6): 973-985.	
		DB	Verma and Somia, "Gene therapy -- promises, problems and prospects," *Nature* 389(6648):239-242 (1997).	
		DC	Wahl *et al.*, "Loss of normal p53 function confers sensitization to Taxol by increasing G2/M arrest and apoptosis," *Nature Medicine* 2(1):72-79 (1996)	
		DD	Weedon, et al., "Apoptosis. Its nature and implications for dermatopathology." Am J Dermatopathol. 1979 Summer;1(2):133-44. Review.	
		DE	Wills *et al.*, "Development and characterization of recombinant adenoviruses encoding human p53 for gene therapy of cancer," *Human Gene Therapy* 5:1079-1088 (1994)	
		DF	Wiznerowicz M, et al. "Double-copy bicistronic retroviral vector platform for gene therapy and tissue engineering: application to melanoma vaccine development." Gene Ther. 1997 Oct; 4(10): 1081-1088.	
		DG	Yeager TR, et al. "Overcoming cellular senescence in human cancer pathogenesis." Genes Dev. 1998 Jan 15; 12(2): 163-174.	
		DH	Yonish-Rouach, et al., "Wild-type p53 induces apoptosis of myeloid leukaemic cells that is inhibited by interleukin-6." Nature. 1991 Jul 25;352(6333):345-7.	
↓		DI	Zhang FL, et al. "Characterization of Ha-ras, N-ras, Ki-Ras4A, and Ki-Ras4B as in vitro substrates for farnesyl protein transferase and geranylgeranyl protein transferase type I." J Biol Chem. 1997 Apr 11; 272(15): 10232-10239.	

Examiner Signature	/Scott Priebe/	Date Considered	06/14/2006

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PTO/SB/08B (08-03)

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 6 of

Complete If Known	
Application Number	10/823,932
Filing Date	April 13, 2004
First Named Inventor	Nielsen, Loretta
Art Unit	~~1695~~ 1633
Examiner Name	~~Lecourciere, K.~~ Priebe, S.
Attorney Docket Number	016930-003713US

U.S. PATENT DOCUMENTS+

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SP	A	WO	95/10514	A1	04-20-1995	Schering Corp.		☐
SP	B	WO	95/28948	A1	11-02-1995	Univ. Texas		☐
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	C	~~HARRIS et al., "Structure and function of the p53 tumor suppressor gene: Clues for rational cancer therapeutic strategies" *J. Natl. Cancer Inst.* (1996) 88(20):1442-1455.~~	
	D	~~NIELSEN et al., "Combination therapy with the Farnesyl protein transferase inhibitor SCH66336 and SCH58500 (p53 Adenovirus) in preclinical cancer models" *Cancer Research* (1998) 59:5898-5901.~~	
	E	~~TISHLER et al. "Microtubule-active drugs Taxol, Vinblastine, and Nocodazole increase the levels of transcriptionally active p53" *Cancer Research* (1995) 55:6021-6025.~~	
		duplicate citations	

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Sheet 1 of 2

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Application Number	10/823,932
Filing Date	April 13, 2004
First Named Inventor	Nielsen, Loretta
Art Unit	~~1614~~ 1633
Examiner Name	~~Lacourciere, K.~~ Priebe, S.
Attorney Docket Number	016930-003713US

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SP	1	WO	98/28948	A1	11-02-1995	Board of Regents, The University of Texas		☐
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Sheet 2 of 2

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Art Unit	1614
Examiner Name	Lacourciere, K.
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SP	2	Tishler et al., Microtubule-active drugs taxol, vinblastine, and nocodazole increase the levels of transcriptionally active p53, Cancer Res. 1995 Dec 15;55(24):6021-5.	

Examiner Signature	/Scott Priebe/	Date Considered	06/13/2006

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] Applicant's unique citation designation number (optional). [2] Applicant is to place a check mark here if English language Translation is attached.